

## An exploration of the barriers to the confident diagnosis of irritable bowel syndrome: A survey among general practitioners, gastroenterologists and experts in five European countries

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Viola Andresen<sup>1</sup>, Peter Whorwell<sup>2</sup>, Josep Fortea<sup>3</sup> and Sébastien Auzière<sup>4</sup>

#### **Abstract**

**Background:** The diagnostic processes for chronic abdominal conditions are challenging. Despite their tendency for diagnostic tests in patients with irritable bowel syndrome (IBS) symptoms, clinicians are encouraged to make a positive diagnosis based on symptom criteria without alarm signs. We explored how European physicians diagnose and manage patients suffering from IBS.

**Methods:** We conducted a vignette-based survey to evaluate the diagnostic approaches in four standardized patients with IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), inflammatory bowel disease (IBD) and chronic constipation (CC). General practitioners (GP, n = 104), gastroenterologists (GE, n = 100) and IBS experts (n = 25) from five European countries participated.

**Results:** Experts showed the highest rates of correct diagnoses (88%–92%) for all cases except CC (only 60%) and were more prone to a positive diagnosis (64%/68% in IBS-C/CC), whereas GEs and GPs tended toward a diagnosis by exclusion (63%/63% and 62%/60% in IBS-C/CC). In the CC vignette, conducting tests was more frequent than prescribing treatment among 44% experts, 63% GEs and 36% GPs. The diagnosis of IBD presented little difficulty for any of the participants.

**Conclusions:** This study highlights the difficulties in confidently diagnosing chronic functional bowel conditions, especially for non-experts, whereas IBD caused little difficulty. Differentiating between IBS-C and CC seemed particularly challenging, even for experts.

#### **Keywords**

Chronic constipation, diagnostic approach, guidelines, IBS-C

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## Introduction

Functional bowel disorders are identified only by symptoms. They include irritable bowel syndrome (IBS), functional bloating, functional constipation, functional diarrhea, and unspecified functional bowel disorders. Inflammatory bowel disease (IBD) and IBS represent two conditions characterized by chronically recurring symptoms of abdominal pain or discomfort and alterations in bowel habits. IBS is a symptomatic motility and sensory disorder of the lower gastrointestinal tract, characterized by abdominal pain or discomfort associated with irregular bowel movements and the absence of detectable structural abnormalities. IBD is characterized by inflammation or ulcerations in the small and/or large intestine, with signs that reflect the

inflammatory process such as rectal bleeding, diarrhea, fever, and weight loss, occasionally associated with extra-intestinal manifestations.<sup>2</sup> The major types of IBD are Crohn's disease, a transmural disease of the gastrointestinal mucosa that can affect the entire gastrointestinal tract from the mouth to the anus, and ulcerative colitis, affecting colonic mucosa only.

<sup>1</sup>Israelitic Hospital, Hamburg, Germany

<sup>2</sup>Wythenshawe Hospital, Manchester, UK

<sup>3</sup>Almirall, Barcelona, Spain

<sup>4</sup>Kantar Health, Paris, France

## **Corresponding author:**

Viola Andresen, Israelitic Hospital, Orchideenstieg 14, 22297 Hamburg, Germany.

Email: v.andresen@ik-h.de

Functional constipation, also called chronic constipation (CC) in many European countries, is another functional bowel disorder that presents as persistently difficult, infrequent, or seemingly incomplete defecation, which do not meet IBS criteria. <sup>1</sup>

The diagnostic processes for functional bowel disorders and the differentiation between functional and IBD can be challenging and uncertain for a variety of reasons. With regard to functional bowel disorders, these include the lack of consistent biological markers. leaving clinicians to rely on patient symptoms alone to make the diagnosis and the non-specificity of the cardinal symptoms of abdominal pain or discomfort as well as the heterogeneity of patients.<sup>3</sup> Despite the tendency of clinicians to order diagnostic tests in the face of IBS symptoms, the Rome III criteria encourage clinicians to make a positive diagnosis on the basis of symptom criteria without alarm signs (e.g. fever, gastrointestinal bleeding, weight loss, anemia, abdominal mass), also emphasizing that for diagnosing functional bowel disorders, laboratory tests are rarely helpful.1

To better understand current diagnostic decision making in IBS, we performed a vignette survey to explore how physicians diagnose and manage patients suffering from IBS. As the overall objective of the survey was to provide for a comprehensive description of physicians' practices in the IBS diagnostic process, no hypothesis was posed prior to the survey setup. This description also includes the level of confidence to set up a diagnosis, to communicate this diagnosis outcome to the patient, to select the appropriate test as well as the confidence to interpret the results of tests and to communicate test results to the patient.

Additional assigned objectives were to measure physicians' beliefs about whether IBS is a diagnosis of exclusion, a positive diagnosis or a combination of diagnoses (exclusion and positive), assessing the diagnostic approach in IBS, namely type of diagnostic tests to be performed and the appropriateness of available diagnostic tests.

Lastly, level of awareness with diagnostic criteria and use of guidelines among physicians were also included in the overall assessment.

#### Methods

## Vignette survey design

This was an online vignette-based questionnaire to evaluate the diagnostic approaches in four standardized patients demonstrating typical cases of irritable bowel syndrome with constipation (IBS-C), irritable bowel syndrome with diarrhea (IBS-D), inflammatory bowel disease (IBD) and functional constipation

(CC). The survey was conducted in five European countries (France, Germany, Italy, Spain and the United Kingdom (UK)) between February and March 2013. IBS Experts, gastroenterologists (GEs) and general practitioners (GPs) were invited to participate through an email with cover letter and a link to the survey, using an online questionnaire platform system. Those agreeing to participate were to answer a 30- to 40-minute questionnaire online. The survey was totally anonymous and the name of the sponsor has not been revealed to participants. The data management of the study was processed in France, and the overall study and data management were covered by the French Data Protection Regulation (CNIL – number 1493177).

The four vignettes were developed based on the Rome III criteria<sup>1</sup> in concert with IBS experts and survey design specialists, to ensure clinical face validity, comprehensibility and comprehensiveness. The vignettes displayed symptom patterns, physical examination, patient's personal and family history and diagnostic results.

The IBS-C vignette described a 57-year-old woman with longstanding intermittent abdominal pain improving after bowel movements, constipation with hard stools and straining and no evidence of alarm signs or symptoms. The IBS-D vignette described a 38-year-old man with longstanding frequent, loose stools, lower abdominal cramping that improved with stool passage, and no evidence of alarm signs or symptoms. The CC vignette described a 42-year-old woman with longstanding constipation, bloating, hard stools and straining, and one or two bowel movements per week. The IBD vignette described a 20-year-old man with abdominal pain and urgent, occasionally bloody diarrhea for three months, which had recently worsened, accompanied by tiredness and significant weight loss. The full vignettes are presented in the Appendix. The vignettes were accompanied by a series of stand-alone questions pertaining to clinical decision making, overall knowledge and perception of IBS, and awareness and use of guidelines.

For each vignette, participants were asked to make a diagnosis and answer questions on the investigation and further management of each case. An overall exploration of participants' perception, attitude and diagnostic approach to IBS was also collected. Most questions were presented with a series of closed-ended questions providing a list of answer choices. These types of questions were commonly in the form of multiple choices, either with one answer or with "check-all-that-apply" options (type of diagnosis, type of test to be conducted, type of treatment to be recommended). The questionnaire also included questions related to level of confidence to set up a diagnosis, to communicate the diagnosis to the patient, to interpret and

communicate test results to patients as well as appropriateness of a test to be conducted. These were presented in an ordinal scale format, where the respondents could decide where to rate their answer along the scale continuum. Some open-ended questions in the form of "Other, please specify" were also offered to ensure that physicians could include other responses not initially anticipated during the design of the survey.

## Sampling frame

Sample of IBS experts. GEs recognized as experts in IBS were identified based on publication in peer-review journals, participation as a key speaker in conferences, training or teaching activities given to peers, and participation in scientific advisory boards. Recruitment was stopped once five experts in each country accepted participation, leading to a total of 25 experts in this group.

Sample of GEs. We surveyed a random sample of 100 GEs from the membership directory of each country's medical association, using a random number generator. In case the random selection process identified a GE already included in the experts group, the selection process was repeated to identify a second individual to avoid duplicates between samples. To be qualified for the survey, GEs had to have at least three years in practice, spend at least 60% of their time in a hospital or clinic and to weekly see 10 or more IBS patients. Recruitment was stopped once 20 GEs in each country completed the questionnaire.

Sample of GPs. We surveyed a random sample of GPs from the membership directory of each country's medical association, using the same process as for the GE group. To be qualified, GPs had to have at least three years in practice, spend at least 70% of their time in a hospital or clinic and to weekly see five or more IBS patients. Recruitment was stopped once 20 GPs in each country completed the questionnaire, leading to a total of 104 GPs.

## Evaluation and statistical analyses

Sample size determination. For each of the two groups, GEs and GPs, a sample size of 100 was required to set the maximum 95% confidence interval for the estimation of proportions to  $\pm 10\%$ .

The expert sample size was limited to 25 because these experts are extremely difficult to recruit.

Diagnosis assessment and perception of the case vignettes. Following each vignette, physicians were asked the following question: "Based on the

information you have just read, do you consider this patient to be more likely ...?" Physicians selected among six options: "a patient with irritable bowel syndrome (IBS)," "a patient with inflammatory bowel disease (IBD)", "a patient with chronic constipation (CC)," "a patient with functional abdominal pain," "Other (please specify)," "Don't know." Those who selected IBS were asked to specify if they were referring to IBS-C or IBS-D. For analysis, we calculated the rates of "correct" and "incorrect" diagnosis and assessed the rates of "do not know." The next question assessed the level of confidence toward the presumed diagnosis at that stage, using a standard nine-point RAND/University of California Los Angeles (UCLA) Appropriateness Scale (RAS) with the following interpretation: scores 1–3 = "generally not confident," 4–6 = "neither not-confident nor confident," 7-9 = "generally confident." <sup>4</sup> Then, physicians were asked how they would "proceed to set up a diagnosis at that stage," choosing between "a positive diagnosis," "a diagnosis of exclusion" or "do not know." Participants were then asked what would be the next action: collect further clinical information or refer to a specialist, conduct tests and/or prescribe a treatment, and the kind of tests or treatments prescribed. In case of tests recommended, participants rated the appropriateness of a range of laboratory, radiographic, and endoscopic tests using RAS and their level of confidence to interpret the test results. For the analysis of the different RAS assessments, we compared mean RAS scores among physicians using analysis of variance, considering a p value < 0.05 as significant.

Overall knowledge and perception of IBS. Stand-alone questions, separated from the vignettes, investigated whether participants believed the diagnosis of IBS to be primarily positive, or by exclusion or both and whether they used guidelines. Participants were also asked to rate their level of awareness of the Rome I, II and III criteria, their overall perception of IBS diagnosis (useful, complex, time-consuming, challenging, uncertain) and their interest regarding information on IBS (sharing experience with peers via seminars, more information about guidelines, more information about diagnostic tests) using a standard nine-point RAS.

General belief about IBS diagnosis. We posed a standalone question separate from the clinical vignette, as follows: "Based on your clinical experience, do you consider IBS, in general, to be...?" Physicians had the choice for a single answer between four options: "IBS is primarily a diagnosis of exclusion (i.e. one or more diagnostic tests should be performed before diagnosing IBS)," "primarily a positive diagnosis,"

"a combination of both (diagnosis of exclusion and positive exclusion)," "Not sure/Do not know."

We first calculated the proportion of respondents in each group who endorsed IBS as a diagnosis of exclusion, and then compared proportions among groups using a  $\chi^2$ -test.

# Knowledge about yield of common diagnostic tests in IBS

Data indicate that the yield of common diagnostic tests in IBS, including colonoscopy, stool studies, inflammatory markers, and thyroid function testing, among others, is low.<sup>5,6</sup> It may be possible that some physicians overestimate or underestimate the diagnostic yield of common diagnostic tests in IBS, and that knowledge about test yield may provide diagnostic decision making. We therefore posed, for each vignette, a series of questions to assess knowledge with diagnostic testing yield in IBS conditions and willingness to prescribe or recommend tests with confidence to the patient with the presumed diagnostic.

Physicians viewed a list of 12 common diagnostic tests and an option for an open-ended space to add additional tests not anticipated in the list shown. Mean number of tests prescribed was assessed between the groups using analysis of variance and a *p* value <0.05 as significant. Differences in physicians' outcomes (in terms of type of tests prescribed and number of tests) were examined using Student's *t*-tests (when comparing groups of physicians with correct diagnostic) and analysis of variance when comparing the three groups (experts, GEs, GPs). A *p* value for all tests was displayed at a significance level of 0.05.

## **Results**

## Sample characteristics

Table 1 shows the characteristics of the survey participants. A total of 229 respondents completed their survey: 25 experts, 100 GEs and 104 GPs. Experts were chosen based on their reputation in the field (=non-random selection) and were therefore not balanced. The randomly selected other physician samples (GEs and GPs) differed slightly among countries, mainly regarding the gender distribution. In most countries, 80% to 95% of GEs were male, while in Spain 50% of GEs were female. The lowest rates of female physicians were found in Italy and the UK. Participating GEs in Italy were older with more years of practice than in the other countries. Experts and GEs were more likely to evaluate a higher number of IBS patients per month than GPs.

## Diagnosis assessment and perception

Ability to make a diagnosis for each patient vignette varied among specialties (Figure 1). Experts showed the highest rates of correct diagnoses (88%–92%) for all vignettes except for the CC vignette, for which the rate of correct diagnosis was 60%. Levels of unknown diagnoses were higher in the GP group, especially for IBS-C and IBS-D.

Table 2 displays the ability to make a diagnosis in each country; all target groups combined. The highest percentage of correct diagnosis of IBS-C was observed in the UK. In Germany and France, more than one physician out of two expressed their inability to diagnose based on information in the vignette. Regarding the IBS-D vignette, share of correct diagnosis was significantly higher in the UK and Spain, and incorrect diagnosis was prevalent in France (22% of physicians), while share of "Unsure" was important for more than one physician out of four in Germany and Italy. Correct diagnosis of CC was higher in Spain, whereas highest share of incorrect diagnosis was found in Italy.

Assessment of IBS-C and CC. CC and IBS-C caused the greatest diagnostic difficulty (Tables 3 and 4).

**Table 1.** Demographic and practice-pattern information of participants

	France	Germany	Italy	Spain	United Kingdom
Participants					
Experts	5	5	5	5	5
GEs	20	20	20	20	20
GPs	21	21	22	20	20
Gender (mal	e/female)				
Experts	4/1	4/1	4/1	4/1	0/5
GEs (%)	90/10	80/20	95/5	50/50	95/5
GPs (%)	76/24	67/33	86/14	65/35	85/15
Mean age (y	ears)				
Experts	52.6	47.0	49.0	50.2	47.2
GEs	43.2	46.0	52.1	43.0	41.3
GPs	49.5	50.7	54.9	49.6	46.0
Mean years	of practice				
Experts	22.2	19.6	23.8	25.4	22.4
GEs	14.3	16.4	21.5	16.0	15.2
GPs	20.7	18.9	27.1	21.6	20.4
Mean numbe	er of IBS r	atients/mon	th		
Experts	34	56	64	40	43
GEs	42	36	50	54	30
GPs	36	22	33	24	35

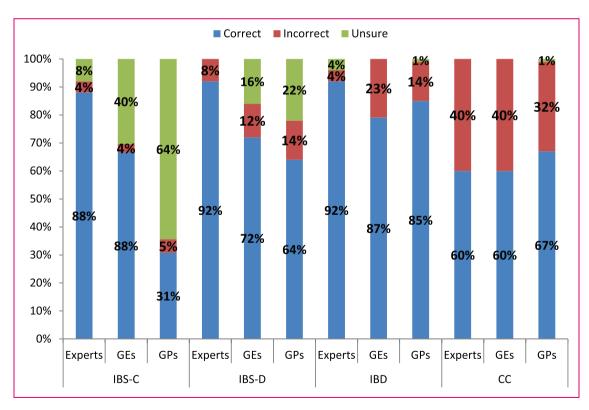
IBS: irritable bowel syndrome; GEs: gastroenterologists; GPs: general practitioners.

A relatively high proportion of GEs and GPs were unsure of the diagnosis based on information provided in the IBS-C vignette, and the CC vignette led to the highest rate of incorrect diagnoses, mainly, because it was misdiagnosed as IBS-C. For both conditions, irrespective of correct or incorrect diagnostic setup, experts were more prone to a positive diagnosis, whereas GEs and GPs tended to make a diagnosis by exclusion. In the IBS-C case, the mean level of confidence to set up a diagnosis was generally higher when the diagnosis was correct. This was also true for GEs in the CC case, while experts had higher diagnostic confidence when incorrectly classifying the CC case as IBC-C. The level of diagnostic confidence in GPs did not differ between correct or incorrect diagnosis. When the diagnosis was correct, the confidence level in communicating IBS-C diagnosis to patients was above 7 (generally confident) and similar between experts, GEs and GPs. For CC, the confidence level was slightly lower but still similar.

For the IBS-C vignette, prescribing a treatment as next action was more frequent than requesting tests. Irrespective of correct or incorrect diagnostic setup, fiber and bulking agents were prescribed by 50% to 60% of physicians, laxatives by 77% of experts and 58% of GEs, antispasmodics by 41% of experts and GPs. A test was requested by 24% experts, 31% GEs and 21% GPs, all being generally confident in how to interpret them. Some GEs and GPs also recommended a colonoscopy even though the patient has presented with normal ileo-colonoscopy results.

For the CC vignette, conducting a test was more important than immediately prescribing a treatment, mainly thyroid function test and colonoscopy, all physicians being generally confident in how to interpret them. A treatment was prescribed by 40% to 52% of physicians, mainly laxatives by experts and GEs.

Assessment of IBS-D and IBD. Based on the IBS-D vignette, 16% of GEs and 22% of GPs were unable to make a diagnosis, this proportion being very low for the IBD vignette (Tables 3 and 4). For IBD, 68% to 80% physicians had a positive diagnosis approach, whereas the proportion of IBS-D diagnosis by exclusion was still high with GEs (62%) and GPs (64%), irrespective of correct or incorrect diagnostic setup. When the



**Figure 1.** Ability to diagnose irritable bowel syndrome with constipation (IBS-C), with diarrhea (IBS-D), inflammatory bowel disease (IBD) and chronic constipation (CC) on the basis of patient history and physical examination findings in patients' vignette. Participants were asked: "Based on the information you just read, do you consider this patient to be more likely...?" The figure depicts the percentages by group giving a correct or incorrect answer or responding "Unsure – need more information." GEs: gastroenterologists; GPs: general practitioners.

Table 2. Ability to make a diagnosis for each vignette, by country

	IBS-C			IBS-D			IBD			S		
	Correct	Incorrect	Incorrect Not known	Correct	Incorrect	Incorrect Not known Correct		Incorrect	Incorrect Not known Correct Incorrect Not known	Correct	Incorrect	Not knowr
France $(n=46)$	43 (29–57) 2 (0–6)	2 (0-6)	24 (40–68)	65 (51-79)	65 (51–79) 22 (10–34) 13 (3–23)	13 (3-23)	85 (75–95)	15 (5-25)	1	65 (51–79) 35 (21–49)	35 (21-49)	1
Germany $(n=46)$	35 (21-49)	7 (0-14)	59 (45-73)	57 (43-71)	7 (43-71) 13 (3-23)	30 (17-43)	78 (66–90)	19 (8-30) 2 (0-6)	2 (0-6)	59 (45-73)	39 (25–53) 2 (0–6)	2 (0-6)
Italy $(n=47)$	51 (37-65)	2 (0-6)	47 (33-61)	64 (50-78)	11 (2-20)	26 (13-39)	87 (77–97)	11 (2-20)	2 (0-6)	55 (41-69)	45 (31–59)	1
Spain $(n=45)$	51 (36-66)	4 (0-10)	44 (29–59)	82 (71–93)	11 (2-20)	7 (0-14)	84 (73–95)	16 (5-27)	ĺ	76 (64–88)	24 (12-36)	ı
UK $(n = 45)$	(42-94) 09	7 (0-14)	33 (19-47)	87 (77-97) 4 (0-10)	4 (0-10)	9 (1-17)	98 (94-100) 2 (0-6)	2 (0-6)	ľ	62 (48-76) 38 (24-52)	38 (24-52)	1

syndrome bowel irritable  $\stackrel{\cdot \cdot}{\simeq}$ with syndrome 2 Kingdom; ⊑ intervals confidence inflammatory bowel disease; CC: chronic constipation with their 95% percentages as expressed

diagnosis was correct, the mean level of confidence to set up a diagnosis and communicate it to the patient was always above 7 and similar between physicians' groups for the IBS-D vignette, whereas IBD led to less confidence, 5.9 to 6.7, because most physicians said they would wait for the result of investigation before making a diagnosis.

After IBS-D diagnosis, a medical treatment was the next action for 84% experts, 73% GEs and 63% GPs, mainly antispasmodics, then fiber/bulking agents. Tests were requested by 16%–20% of physicians. For the IBD vignette, the next action after diagnosis was to conduct tests (colonoscopy in all cases); GPs were 57% likely to request a test and 55% likely to collect more information or refer the patient to a GE.

## Overall knowledge and perception of IBS

IBS is considered by experts as mainly a combination of positive and exclusion diagnosis, whereas GEs and GPs as mainly a diagnosis of exclusion (Figure 2). Most physicians refer to guidelines, with the proportion among experts being higher than GEs or GPs. While experts would rather refer to international guidelines, GEs and GPs are more inclined to refer to national guidelines (Figure 2). The Rome III criteria are the most prevalent diagnosis criteria; the share of awareness among experts is overriding and is significantly higher compared to other groups (96% vs. 73% GEs; and vs. 15% GPs). Awareness mean score is significantly higher for experts (8.4 vs. 7.1 GEs and vs. 3.3 GPs), with more than half of them scoring the highest score: 9 (median =9 for "know very well"). Whatever criteria tested, the level of awareness among GPs is significantly lower compared to GEs or to experts.

Experts and GEs show substantial interest toward sharing experience with peers via seminars. GPs expressed less interest in sharing experience than in having more information on diagnosis tests (Figure 2).

The IBS diagnosis process (Figure 3) is overall perceived as very useful. This perception is reinforced among experts. For most physicians, experts or non-experts, the diagnostic process appears to be time consuming, complex and challenging. In a significant proportion, GPs associate the IBS diagnosis process with uncertainty.

## **Discussion**

The diagnostic processes for chronic abdominal conditions and differentiation between functional and IBDs remain challenging. Knowledge of real-life diagnostic process allows for evaluation of the conformity of practices with the current guidelines and their applicability.

Table 3. Diagnosis assessment and perception

	Irritable bow	Irritable bowel syndrome with constipation	h constipation	Irritable bow	Irritable bowel syndrome with diarrhea	ith diarrhea	Inflammat	Inflammatory bowel disease	lisease	Chronic c	Chronic constipation	
Type of physician	Experts	GEs	GPs	Experts	GEs	GPs	Experts	GEs	GPs	Experts	GEs	GPs
Diagnosis assessment												
Correct %	88	26	31	92	72	79	92	87	85	09	09	29
95% CI	75-100	99-97	22-40	81-100	63-81	55-73	81-100	80-94	78-92	41-79	20-70	28-76
Incorrect %	4	4	5	œ	12	14	7	23	14	04	04	32
95% CI	0-12	8-0	1-9	0-19	6-19	7-21	0-19	15-31	8-22	21-59	30-50	24-42
Unsure %	8	07	49	0	16	22	7	0	1	0	0	1
95% CI	0-19	30-50	55-73		9-23	14-30	0-12		1-3			1-3
Fisher exact test p value <0.0001	e <0.0001			0.037			0.059 (NS)			0.538 (NS)	(5	
Confidence to set-up diagnosis, RAND/UCLA appropriateness scale <sup>a</sup> (mean ± SD) Correct disanosis 77+08 74+13 69+11	gnosis, RAND/UC	CLA appropriaten	less scale <sup>a</sup> (mean =	± SD)	74.10	7 1 + 1 1	6.0+13	67+14	+ c 4	4 + 1 4	7.0+13	67+11
Incorrect diagnosis	ND	$6.6\pm1.3$	$6.1 \pm 1.5$	N Q	$6.7 \pm 1.8$	$5.9 \pm 1.4$	ND	ND	ND	$7.3 \pm 0.6$	$6.2 \pm 1.5$	$6.5\pm1.4$
Diagnosis process when diagnosis is correct/incorrect, % Positive 68/ND 39/30	diagnosis is corr 68/ND	rect/incorrect, % 39/30	41/31	57/ND	42/25	36/24	83/ND	78/ND	72/ND	01/19	45/25	39/32
By exclusion	32/ND	29/68	29/92	43/ND	58/71	89/89	17/ND	20/ND	24/ND	33/30	55/75	29//2
Do not know	-/ND	2/2	3/4	-/ND	4/-	1/8	-/ND	2/ND	dN/4			4/3
Confidence to communicate diagnosis to the patient – RAND/L Correct diagnosis 7.8 $\pm$ 0.7 7.5 $\pm$ 1.3 7	ate diagnosis to 7.8 $\pm$ 0.7	the patient - RA 7.5±1.3	ND/UCLA appropr 7.2 ± 0.8	JCLA appropriateness scale (mean $\pm$ SD) $^a$ .2 $\pm$ 0.8 7.7 $\pm$ 0.7 $\pm$ 1.5 $\pm$ 1.0	mean $\pm$ SD) $^a$ 7.5 $\pm$ 1.0	$7.1\pm1.1$	$5.9\pm1.6$	$6.6\pm1.6$	$6.1\pm1.5$	$6.6\pm1.5$	$7.0\pm1.3$	$6.8 \pm 1.1$
Incorrect diagnosis	ND	$6.8 \pm 0.8$	$6.4\pm1.0$	$5.0 \pm 2.0$	$6.7\pm1.2$	$6.4\pm1.4$	ND	$5.6\pm1.8$	$6.3\pm1.8$	$7.4\pm0.7$	$6.5 \pm 1.4  6.6 \pm 1.4$	$6.6\pm1.4$

ND: not determined, due to a too low number of participants; 95% CI: 95% confidence intervals; NS: not significant; GEs: gastroenterologists; GPs: general practitioners.

\*RAND/University of California Los Angeles (UCLA) Appropriateness Scale: scores 1-3 = "generally not confident," 4-6 = "neither not-confident nor confident," 7-9 = "generally confident."

Table 4. Patient's management

	Irritable bowe	Irritable bowel syndromewith constipation	constipation	Irritable bow	Irritable bowel syndrome with diarrhea	th diarrhea	Inflammate	Inflammatory bowel disease	isease	Chronic co	Chronic constipation	
Type of physician	Experts	GEs	GPs	Experts	GEs	GPs	Experts	GEs	GPs	Experts	GEs	GPs
Next action, %												
Prescriptions	72	89	49	48	73	63	4	12	10	<b>†</b> †	04	52
Tests	24	31	21	16	20	17	88	91	57	77	63	36
Collect information/refer 12	12	13	25	12	17	27	28	21	55	20	14	28
Tests likely to be conducted for the patient when diagnosis is	d for the patien	it when diagnosis	s is correct/incorrect, %	ect, %								
Thyroid function tests	32/-	18/34	ı	-/6	ı	15/-	1	1	1	53/30	37/37	34/38
Colonoscopy	ı	-/34	-/98	1	-/21	-/27	100/-	-/66	-/26	33/-	52/58	39/38
Blood count	ı	T	-/28	1	18/-	ı	83/-	-/89	ı	-/50	-/58	-/38
Sedimentation rate	ı	ī	1	1	ı	ı	ī	ı	-/49	1	ı	ı
No new tests	I	ı	-/45	ı	-/43	-/42	ı	ı	ı	1	ı	ı
Confidence to interpret test results - RAND/UCLA appropriateness scale (mean $\pm$ SD) $^{ m a}$	t results - RAN	D/UCLA appropri	ateness scale (me	$an \pm SD)^a$								
Correct diagnosis	$\textbf{7.8} \pm \textbf{1.0}$	$\textbf{7.3}\pm\textbf{1.3}$	$6.8\pm1.1$	$7.8 \pm 0.8$	$7.8\pm1.0$	$7.3 \pm 1.2$	$8.2 \pm 0.7$	$8.1\pm0.9$	$7.5\pm1.1$	$7.3\pm1.3$	$7.7\pm1.2$	$\textbf{7.3} \pm \textbf{1.2}$
Incorrect diagnosis	ND	$7.7\pm1.3$	$6.8\pm1.6$	$6.5\pm2.5$	$6.2\pm1.3$	$6.7\pm0.9$	ND	$6.8\pm0.5$	$7.0\pm1.2$	$\textbf{7.6} \pm \textbf{0.9}$	$\textbf{7.3} \pm \textbf{1.1}$	$7.1\pm1.3$
Class of treatment recommended/prescribed when diagnosis is correct/incorrect , %	nended/prescribe	ed when diagnos	is is correct/incor	rect, %								
Laxatives	81/-	52/65	-/51	ı	ı	ı	1	ı	ı	89/63	79/89	-/89
Fiber/bulking agents	52/-	63/35	71/60	22/-	30/33	27/23	ī	T	1	33/-	34/44	55/40
Antispasmodics	ì	1	-/09	61/-	09/99	69/73	-/09	1	33/-	1	1	1
Aminosalicylates	ī	ı	1	1	1	ī	-/09	-/89	33/-	1	ı	ı
Corticosteroids	1	ī	ı	1	ı	ī	ı	-/04	1	1	ı	ı
Prokinetics	I	I	I	ı	1	1	1	1	ı	-/63		

GEs: gastroenterologists; GPs: general practitioners.  $^{a}$ RAD) Appropriateness Scale (RAS): scores 1-3 = "generally not confident,"  $^{4}$ -6 = "neither not-confident nor confident," 7-9 = "generally confident."

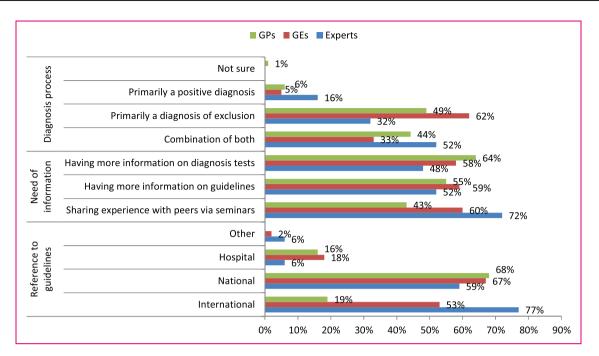


Figure 2. Overall knowledge and needs in irritable bowel syndrome. Participants were asked: For diagnosis process: "Based on your clinical experience, do you consider IBS, in general, to be?" For the interest regarding information on IBS: "To what extent would you be interested in the following aspects using a scale of 1–9, where 1 means 'not at all' and 9 'very'?" Percentages presented represent the rates of participants who gave a score of 7–9. For reference to guidelines: "During IBS diagnosis process, if you refer to guidelines, which guidelines do you generally refer to?" The figure depicts the percentages by group for each possible answer.

IBS: irritable bowel syndrome; GPs: general practitioners; GEs: gastroenterologists.

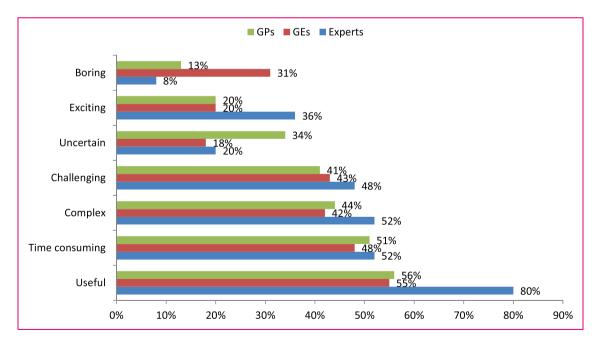


Figure 3. Overall perception of diagnosis process. Participants were asked: "Please assess your overall perception of IBS diagnosis process, using a scale from 1 to 9, where 1 means 'not at all' and 9 'very." The figure depicts the percentages by group for each possible answer. Percentages represent the rates of participants who gave a score of 7–9.

IBS: irritable bowel syndrome; GPs: general practitioners; GEs: gastroenterologists.

This study highlights the difficulty experienced by GPs, GEs and experts in confidently diagnosing conditions such as IBS. Participants generally regarded the IBS diagnostic process as time consuming, complex and challenging.

Concerning IBS knowledge, GPs were less aware of guidelines and they overall regarded IBS as a diagnosis of exclusion. Among GEs, however, there was a discrepancy between guidelines and clinical practice: Despite a high rate of awareness of the Rome III guidelines, IBS was still perceived to be a diagnosis of exclusion. In contrast, most experts with high guidelines awareness regarded IBS as a positive diagnosis or a combination of a positive diagnosis and diagnosis by exclusion.

Except for experts, a significantly high proportion of physicians were unable to make a diagnosis based on information provided in the patient vignette, especially for the IBS-C patient vignette and to some extent IBS-D, which is indicative of a general lack of confidence in making the diagnosis. On the other hand, experts and GEs were more likely to misdiagnose CC as IBS-C than GPs. The latter may actually reflect a more general view of these two disorders to be different manifestations of the same underlying disease, mostly considered as IBS. In fact, several studies have shown a large overlap between these two disorders, 7-13 and it may often be neither possible nor necessary to differentiate between the two. Still, current diagnostic guidelines such as the Rome III criteria do differentiate between the two disorders, where absence of abdominal pain would be the main differentiating sign of CC versus IBS-C. The awareness of this differentiation may also be of importance for the use of medical therapies, where some drugs are developed and approved only for CC and others only for IBS-C.

With regards to diagnostic approaches, experts were more likely than GEs and GPs to endorse a positive approach to the diagnosis of IBS, IBD or CC, whereas GEs and GPs would rather adopt a diagnosis by exclusion approach indicating an important discrepancy between the practice of experts and "generalists." However, despite a high rate of exclusion diagnoses, the need for additional investigations remained rather low for IBS-C and IBS-D. This may partly be explained by the fact that the IBS patients in the vignettes have already presented with diagnostic workups so that the physicians could have rated their diagnosis as "diagnosis of exclusion" at that stage. But this could also partly reflect a different attitude toward the meaning of a "positive diagnosis." To an expert, a positive approach typically means emphasizing the certainty of the diagnosis to the patient but still accepting the need for some investigation if necessary, whereas the generalist is more likely to prefer exhaustive investigation followed by a less certain diagnosis: "The tests are all negative therefore it is probably IBS." This discrepancy may reflect valid concerns about the incomplete understanding of the pathophysiology of IBS. Indeed, an increasing body of evidence suggests molecular and cellular alterations at the mucosal level, changes in gut flora, disturbances of super-ordinated regulatory systems, and increased prevalence of psychological comorbidities.<sup>14</sup>

IBD, as an inflammatory process, was easily recognized, but colonoscopy and blood tests were deemed necessary to confirm the diagnosis. The CC case presented with few prior test results and probably therefore led 40% to 45% of experts and GEs to request colonoscopy and thyroid testing, underlining once more the difficulty experienced by physicians and their fear of misdiagnosing a more severe condition.

It is of note that the level of confidence in the different diagnoses and in communicating the diagnosis to patients was similar among experts, GEs and GPs. All physicians were generally confident in announcing the diagnosis to the patient except for IBD, for which they would wait for investigation results.

Interestingly, there were some country-related variations in the ability to make a diagnosis based on the information in the vignettes. This may reflect differences in health care systems, specifically differences in national guidelines and practice approaches as well as the availability and costs of diagnostic tests. However, this was not specifically assessed in our study, which is a limitation of this survey. Hence, it would be interesting for future, most likely not purely survey-based studies to additionally assess health care system-related factors including cost issues to be able to compare cost-percase estimations among the different countries.

Another possible limitation of this survey is that responses may not reflect the real-life diagnosis-making process. The true process of care may theoretically be better evaluated by direct observation, but in this approach, physicians tend to alter their practice when they know they are being observed. Survey-based clinical vignettes have been validated as an accurate surrogate for both chart abstraction and standardized patients, <sup>15</sup> and are thus widely recognized to be a valid, reliable, practical, and cost-effective technique to assess process of care.

Another limitation is that we were unable to compare participant and non-participant characteristics, no master files being available for each of the surveyed countries, therefore the sample representativeness and a generalizability of our results may be questioned. However, the comparability between countries was established.

Finally, our distinction of expert and non-expert, although based on explicit criteria, may fail to

acknowledge the fact that many community providers who manage IBS on a daily basis might have a higher clinical experience than some academic opinion leaders.

Overall, this study highlights the difficulties in confidently diagnosing chronic bowel conditions. Where an inflammatory disease caused little difficulty, all functional symptoms were regarded as difficult to diagnose, especially by non-experts. Differentiating between IBS-C and CC seemed particularly challenging even with reference to guidelines. Such criteria as Rome III are extremely useful for research purposes but are complicated and may not be easily applicable in a normal clinical setting. While guidelines may not necessarily improve diagnostic ability, they may partly influence the perception of the diagnostic approach. High rates of diagnostic resource use may be driven by potentially modifiable knowledge deficits, beliefs, and attitudes regarding IBS.

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#### **Conflicts of interest**

V Andresen has received lecture fees from Almirall, Abbvie, Aptalis, Ardeypharm, Norgine, Shire, Mundipharma and Falk; and is a consultant for Almirall, Astra Zeneca, Norgine and Shire.

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## Appendix-Typical patient vignettes

Irritable bowel syndrome with constipation (IBS-C) vignette

#### Presentation

- A 57-year-old female secretary presents with abdominal discomfort and intermittent dull and occasionally "crampy" abdominal pain
  most days, ongoing for several years.
- Abdominal discomfort and pain are often improved after bowel movements.
- The patient has bowel movements around two to four times a week and describes them as hard and lumpy; she needs to strain hard to move her bowels.

#### Patient history

- Appendectomy (1974)
- Mild essential hypertension
- Allergic to penicillin
- Frequent consultations for abdominal pain symptoms and hemorrhoids over the last year.
- The patient is slightly overweight. No major weight change in the last year.
- Patient smokes and reports moderate alcohol intake.
- The patient states she eats a healthy diet with fresh fruit and vegetables every day.

#### Family history

No family history of gastrointestinal cancer or ovarian cancer.

#### Medication

Low-dose beta-blocker prescribed for mild essential hypertension.

#### Physical examination

- 1.68 meters (5 feet, 6 inches) and 72 kg (11 stone, 4 pounds, 158 pounds), body mass index (BMI) 25.5
- Normal vital signs (blood pressure (BP) 125/80 mmHg)
- Mild tenderness to palpation in the center of the abdomen
- Rectal examination shows hard stool in the vault that is guaiac negative
- Normal sphincter tone and perineal descent

## Previous medical examinations

- · Previous examinations have shown no abnormalities in blood count, inflammatory markers, urine tests, thyroid function test
- Previous gynecological examination revealed no abnormalities
- · Abdominal ultrasound and ileo-colonoscopy normal

Irritable bowel syndrome with diarrhea (IBS-D) vignette

#### Presentation

- . A 38-year-old male, carpenter, presents with frequent bloating, abdominal cramping and soft or liquid stools three to five times a day.
- The bowel movements are predominantly in the morning hours and are often preceded by urgency.
- Abdominal cramps, but not the bloating, improve after bowel movements.
- The patient has not experienced bloody diarrhea, nor fever nor weight loss.

## Patient history

- The patient is normal weight. No weight change in the past year.
- Non-smoker. Patient reports moderate alcohol intake.
- · Regular exercise (running or biking almost daily).
- Patient likes to eat meat and white bread. He reports worsening of symptoms when eating much vegetable, fruit or fiber.
- The symptom onset was three years ago after the patient has contracted a campylobacter jejuni enteritis.

#### Family history

Grandmother died of colon cancer. Father had colonic polyps.

#### Medication

Loperamide and peppermint oil on demand.

(continued)

#### Continued

#### Physical examination

- 1.84 m (6 feet, 4 inches) and 78.0 kg (12 stone, 3 pounds, 172 pounds)
- Normal vital signs (BP 125/80 mmHg)
- Normal body temperature (36.8°C)
- Mild tenderness to palpation in the center and left lower quadrant of the abdomen.
- Rectal examination shows soft stool in the vault that is guaiac negative.

## Previous medical examinations

- No abnormalities in blood count, inflammatory markers, urine tests, thyroid function test.
- Stool examinations showed no bacterial or parasite pathogens.
- · Calprotectin in the stool was normal.
- Transglutaminase-antibodies were normal.
- · Pancreatic function test was normal.
- H2-breath tests showed no signs of lactose- or fructose-malabsorption or small bowel bacterial overgrowth.
- Ileo-colonoscopy with biopsies was macroscopically and histologically normal.
- · Abdominal ultrasound was normal.

#### Inflammatory bowel disease (IBD) vignette

#### Presentation

- A 20-year-old male student presents with worsening diarrhea and abdominal pain for last seven days.
- · Diarrhea urgent and occasionally bloody.
- . The patient reports loose stools and an increase in stool frequency to two to three times daily from once daily over last three months.
- · Pain is described as cramp-like, intermittent, moderate in intensity, affects most of the abdomen and can be worse after eating.
- The patient complains of constantly feeling tired and with decreased appetite. He has lost 6.3 kg (1 stone) over the last three months.

#### Patient history

- Eczema
- Travel vaccinations: hepatitis A, hepatitis B, typhoid, diphtheria, cholera.
- Gastroenteritis 12 months ago
- Patient smokes and drank heavily prior to current illness.

## Family history

No family history of gastrointestinal cancer or other significant medical conditions.

### Medication

No recent antibiotic use.

## Physical examination

- 1.85 m (6 feet, 1 inch) and 68.0 kg (10 stone, 9 pounds, 149 pounds)
- Vital signs normal.
- Patient appears pale.
- Abdomen tender on palpation in lower left quadrant, without guarding or rigidity. No distension or palpable masses.
- Rectal exam normal.

## Previous medical examinations

Stool guaiac positive.

Stool cultures negative.

## Chronic constipation (CC) vignette

#### Presentation

- A 42-year-old female accountant complains of having infrequent bowel movements with hard and difficult-to-pass stools.
- Symptoms have been present for many years but have gotten worse over time.
- She moves her bowels on average once or twice a week.
- She often feels full and bloated, especially when she has not had a bowel movement for some days.

#### Patient history

- Previous consultations for constipation symptoms over the last 12 months.
- No known allergies.
- Pneumonia treated with amoxicillin (three years ago).
- No fever, chills, nausea, vomiting, unexplained weight loss or rectal bleeding.
- Patient reports feeling stressed due to pressure at work.
- Non-smoker, little alcohol consumption.
- No regular physical activity.

#### Family history

- No family history of gastrointestinal cancer.
- Patient's mother has recently been diagnosed with Alzheimer's disease.

#### Madication

- Recent prescriptions of Fybogel and Macrogol.
- The patient complains that Fybogel made her feel more bloated and distended without adequately relieving constipation.

## Physical examination

- 1.62 m (5 feet, 3 inches) and 78 kg (172 pounds, 12 stone, 4 pounds; BMI 29.7)
- Normal vital signs.
- No pain or tenderness to palpation of the abdomen.
- · Rectal examination shows hard stool in the vault, guaiac negative.
- Normal sphincter tone and perineal descent.

## Previous medical examinations

No abnormal findings in blood and urine laboratory test at previous consultations.